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United States General Accounting Office Washington, D.C. 20548

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Resources, Community, and Economic Development Division

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December 21, 1990

The Honorable Patrick J. Leahy Chairman, Committee on Agriculture, Nutrition and Forestry United States Senate

The Honorable Tom Harkin United States Senate

The Honorable Dennis E. Eckart House of Representatives

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This report responds to your requests to provide an overall perspective on federal efforts to ensure food safety and quality. For the purposes of our review, we defined food safety activities as those carried out to ensure that food is safe, sanitary, wholesome, and properly labeled. Food quality activities are defined as those establishing standards of quality and condition, grading food products according to the standards, certifying that food products meet the standards, and inspecting food products for compliance with the standards.

As agreed with your offices, this report provides information on (1) the statutory responsibilities, programs, activities, staffing, and budgets of the federal agencies involved with food safety and quality; (2) the interagency agreements used by the agencies to cooperate in meeting their statutory duties; (3) the ways in which funding and staffing levels have changed during the 1980s relative to the agencies' work loads; and (4) the issues that federal officials believe will be critical for food safety and quality in the 1990s. As agreed, we did not evaluate how well the agencies carried out their responsibilities or whether there was duplication of effort or gaps in coverage among agencies.

Results in Brief

• The fragmented, complex federal food safety and quality regulatory system consists of as many as 35 different laws and involves 12 federal agencies. Of the 12 agencies, 6 have the major roles in carrying out food safety and quality activities. They are the Food and Drug Administration (FDA), which is part of the U.S. Department of Health and Human Services (HHS); the U.S. Department of Agriculture's (USDA) Agricultural Marketing Service (AMS), Federal Grain Inspection Service (FGIS), and Food Safety and Inspection Service (FSIS); the Environmental Protection Agency (EPA); and the National Marine Fisheries Service (NMFS),

which is part of the U.S. Department of Commerce. Collectively, these agencies are responsible for assuring the consumer that foods are pure and wholesome, safe to eat, and produced under sanitary conditions. In fiscal year 1989 these six agencies devoted over \$800 million and almost 17,000 staff years to their food safety and quality activities. FDA and USDA together had about 92 percent of the funding and about 95 percent of the staffing.

- The fragmentation of responsibility for carrying out food safety and quality laws has required extensive efforts by federal regulatory agencies to coordinate their activities. We identified 51 different interagency agreements involving the six agencies directed at avoiding wasteful duplication of effort, preventing gaps in coverage, and avoiding conflicting actions.
- The four agencies that had comparable data—EPA, FDA, FGIS, and FSIS—had less staff and less funds (in constant dollars) available to carry out their food safety and quality activities in fiscal year 1989 compared with 1980. Moreover, all four agencies generally had larger work loads related to food safety and quality in fiscal year 1989 than in 1980. Two agencies—AMS and NMFS—did not have comparable data for their food safety and quality activities for fiscal years 1980 and 1989. However, available data for AMS show that funding (in constant dollars) decreased from fiscal year 1980 to 1989 and that staffing decreased from fiscal year 1985 to 1989. NMFS' funding data for the early 1980s were not available. However, NMFS' staffing level increased between the early 1980s and 1989, while the amount of seafood it inspected decreased between 1981 and 1989. We did not evaluate the impact that the changes in funding, staffing, and work load had on the effectiveness of the agencies' food safety and quality activities.
- Officials of the agencies generally agreed that microbiological contamination (e.g., bacteria and viruses) and pesticide/chemical contamination of foods will be the critical food safety and quality issues of the 1990s. Beyond these two issues, concerns were focused primarily on issues that pertained to each agency's area of jurisdiction or responsibility.

Background

USDA estimates that U.S. consumers purchased about \$513 billion worth of food in 1989. Federal laws place on manufacturers the basic responsibility for precessing food under sanitary conditions and for producing wholesome and safe products. But consumers also rely on the U.S. food safety and quality regulatory system, which includes state, local, federai, and international agencies, to ensure the quality and safety of food products. Because of the combined efforts of the food industry and the regulatory agencies, the U.S. food supply is generally recognized as one

of the safest in the world. Nonetheless, the Centers for Disease Control estimates that about 6 million cases of illness and 9,000 deaths from foodborne disease occur each year in the United States.

Federal legislation regulating food safety and quality has evolved piece-meal over many decades to address particular risks to public health. For example, the first federal comprehensive food law—the Pure Food and Drug Act—became law in 1906. This act and other old food safety and quality statutes have been amended over time and new legislation has been enacted to address specific concerns about the safety of the food supply, such as the use of chemicals to color and preserve food, the use of drugs in food animals, the large-scale use of pesticides on food crops, and technological changes in handling, processing, and packaging food.

The Federal Food Safety and Quality Regulatory System Is Complex and Fragmented

The six agencies perform a broad array of activities relating to food regulation. Their programs

- set standards for what processed foods should contain;
- approve facilities, equipment, and processes used in preparing foods;
- approve additives, animal drugs, or pesticides before their marketing or use;
- set tolerances for acceptable amounts of pesticides and other chemical residues in food;
- inspect food and food processing facilities, including testing food for illegal residues;
- determine what information labels should contain and what packaging is acceptable; and
- monitor state and local inspection programs for food retail and service establishments.

In carrying out their legislative responsibilities, the six agencies often perform similar types of activities. For example, most agencies conduct food-related research, inspect food processing establishments, collect and analyze food samples for pesticide and other chemical contaminants, and develop food standards. Their specific responsibilities are as follows:

FDA ensures that domestic and imported food products (except for meat
 and poultry products) are safe, sanitary, mutritious, and wholesome and
 are honestly labeled. FDA shares responsibility for egg products with

AMS; the latter agency inspects egg products plants, while FDA has jurisdiction over restaurants, food-manufacturing plants, and similar establishments that serve eggs or use them in their products. FDA is also responsible for pre-approval and surveillance of animal drugs and food additives in feeds marketed in interstate commerce.

- FSIS ensures that meat and poultry products moving in interstate and foreign commerce for use as human food are safe, wholesome, and correctly marked, labeled, and packaged.
- AMS ensures the safety of shell eggs moving in consumer channels and
 egg products produced by processing plants involved in intrastate, interstate, and foreign commerce. AMS also performs food quality services
 such as commodity standardization, inspection, and grading services
 upon request for dairy, egg, fruit, meat, poultry, and vegetable products.
- FGIS inspects corn, sorghum, and rice for aflatoxin (a natural contaminant considered to be carcinogenic) as well as the quality of domestic and exported grain, rice, and related commodities.
- EPA regulates all pesticide products sold or distributed in the United States and establishes tolerances (maximum legal limits) for pesticide residues in or on food commodities and animal feed.
- NMFS conducts a voluntary seafood inspection and grading program, which is primarily a food quality activity, and performs research on seafood safety.

The federal resources devoted to food safety and quality activities vary considerably among the six agencies. Table 1 shows their fiscal year 1989 funding and staffing levels. FSIS—the largest in terms of resources used—accounted for about 56 percent of the total funds and 62 percent of the total staff years used by these agencies in fiscal year 1989. In contrast, FDA's share amounted to about 19 percent of the total funds and about 14 percent of the staff years. NMFS had the least resources, accounting for only about 1.5 percent of both the total funds and total staff years.

Table 1: Six Principal Federal Agencies' Fiscal Year 1989 Funding and Staffing Levels

	FY 1989	funding	FY 1989	staffing
Agency	Amount	Percent	Number	Percent
FSIS	\$457	55.7	10,399	61.7
FDA	158	19.2	2,337	13.8
AMS	97	11.8	2,372	14.1
EPA	55	5.7	624	3.7
FGIS	42	5.1	860	5.1
NMFS	12	1.5	265	1.6
Total	\$821	100.0	16,857	100.0

To facilitate the use of the information we developed on federal efforts to ensure food safety and quality, we compiled several summary tables that characterize these activities in different ways. We have included these tables as appendixes to this report. Appendix I lists the principal food safety and quality legislation and the federal agencies responsible for implementing the legislation. Appendix II provides major provisions of principal food safety and quality legislation. Appendix III provides information on the legislative responsibilities, programs, and fiscal year 1989 staffing and funding levels for the principal agencies. Appendix IV lists food safety and quality activities carried out by federal agencies. Appendix V shows which agencies regulate, monitor, or perform quality grading services for various food industries.

Federal Interagency Coordination Is Extensive

In light of the many laws and agencies involved in regulating the U.S. food supply, it is essential that the federal government coordinate its activities. Coordination is needed, among other things, to help cosure effective use of resources, avoid duplication of effort prevent gaps in coverage, and avoid conflicting actions.

According to our analysis, 51 written into agency agreements are aimed at addressing potential problems in federal food safety and quality. The agreements vary in scope, detail, and master of agencies involved. For example, some are between two agencies and are limited in scope, such as the agreement between AMS and FDS involving the effective centrol of the afortoin problem in peanuts aestined for consumer consumption. Other agreements are with several agencies and are broader in 8 tope, such as the agreement among AMS, EPA, FDA, and PSIS concerning residues of drugs, pesticides, and environmental contaminants in food, (See app. VI for examples of the agreements.)

These interagency agreements are necessary for a variety of reasons. The following two examples illustrate the nature of the agreements:

- EPA has statutory responsibility for establishing tolerances for pesticide residues on food and animal feeds, while FDA is responsible for establishing tolerances for other chemical residues on food. Statutory responsibility for enforcing the tolerances is vested in FSIS for meat and poultry products, AMS for egg products, and FDA for all other foods. AMS, EPA, FDA, and FSIS have an interagency agreement that establishes the working relationships for promoting more effective, efficient, and coordinated federal regulatory activities concerning residues that may adulterate food. EPA is to notify FDA and USDA of any pesticide use it encounters that may have resulted in residues that adulterate human food or animal feed. FDA is to notify (1) EPA of possible misuse of pesticides or chemical substances that may indicate a violation of EPA's laws and (2) USDA of illegal residues of drugs, pesticides, or environmental contaminants in human food or animal feed that indicate that the residues may also be present in meat, poultry, or egg products. USDA is to notify FDA of findings of illegal residues in edible meat, poultry, or egg products and to keep FDA and EPA informed of all FSIS and AMS sampling and testing programs for illegal residues.
- Fishery products plants that are under NMFS voluntary inspection contracts are also subject to FDA inspection under the Federal Food, Drug, and Cosmetic Act. The agreement covering these plants provides that NMFS is to apply appropriate FDA requirements pertaining to good manufacturing practices, labeling, food additives, tolerances, standards of identity, minimum quality, and fill of containers. NMFS is to notify FDA if inspections reveal violations of mandatory FDA requirements, and FDA is to notify NMFS of any official FDA actions to seize fishery products processed or packed in NMFS-inspected plants.

FDA had the most interagency agreements because it is responsible for the safety of most food types and uses the personnel and results of other federal agency inspection and quality-grading programs to help carry out its food safety mission. In fiscal year 1989 FDA had 27 interagency agreements relating to food safety and quality with other federal agencies, primarily USDA.

Federal Resources Have Decreased While Work Loads Have Increased in the 1980s

Available data show that the resources of four agencies have decreased since 1980 while their work loads related to food safety and quality have increased. We requested that the six agencies provide data on their food safety and quality resources and inspection activities for fiscal years 1980-89. Four agencies—EPA, FDA, FGIS, and FSIS—were able to provide us with comparable staffing and funding data for 1980 and 1989 to allow a comparison of the resources available for those 2 years. (App. VII provides the details of the data submitted.)

Each of the four agencies had less staff available to carry out its food safety and quality activities in fiscal year 1989 than in 1980. FGIS had about 58 percent less, EPA about 17 percent less, FDA about 8 percent less, and FSIS about 6 percent less staff in fiscal year 1989 than in 1980. Although EPA, FDA, and FGIS had smaller staffs in fiscal year 1989 than in 1980, their staffs have increased since fiscal year 1985.

Each of the four agencies also had less funds (in constant 1989 dollars) available in fiscal year 1989 than in 1980. FGIS had about 50 percent less funds, EPA and FDA each about 8 percent less, and FSIS about 3 percent less.

Despite less staff and less funds in fiscal year 1989, these four agencies generally had larger work loads in fiscal year 1989 than in 1980. For example, FSIS inspected about 38 percent more pounds of meat and poultry products and analyzed about 182 percent more laboratory samples in fiscal year 1989 than in 1980. FGIS inspected about 7 percent more tons of grain in fiscal year 1989 than in 1980.

Two agencies, AMS and NMFS, did not have comparable data for their food safety and quality activities for fiscal years 1980 and 1989, principally because of changes in organization and/or responsibilities or the destruction of data pursuant to agency records retention guidelines. However, available data for AMS' two largest programs, which accounted for about 95 percent of the agency's fiscal year 1989 funding, show that AMS' funding decreased about 6 percent (in constant dollars) from fiscal year 1980 to 1989 and that its staffing decreased about 3 percent from fiscal year 1985 to 1989. NMFS' funding data for the early 1980s were not available. However, NMFS' direct inspection staff increased about 30 percent from the early 1980s to 1989. During this time the average number of plants participating in the voluntary seafood inspection program increased by about 50 percent, while the pounds of seafood NMFS inspected decreased about 10 percent from 1981 to 1989.

Critical Food Safety and Quality Issues of the 1990s

When asked what they believed would be the critical food safety and quality issues of the 1990s, officials of the six agencies most often mentioned microbiological contamination and pesticide/chemical contamination of foods. Several agencies also expressed concern about issues such as the safety of new food processing technology; the safety of new technology such as vacuum and modified-atmosphere packaging; nutritional and other product labeling; and the public's perception of food safety.

In addition to broader issues, most agencies were concerned about critical food safety and quality issues that pertained to their areas of jurisdiction or responsibility. For example, NMFS was concerned about adequate water of acceptable quality in seafood processing facilities. EPA had several issues relating to the present law governing pesticide regulation, such as the need for improved authority to remove questionable pesticides from the market and enhanced enforcement authority. (See app. VIII.)

Other Federal Agencies Involved With Food Safety and Quality

In addition to the six major agencies, six other federal agencies carry out important, but less significant, food safety and quality activities. Their responsibilities and the fiscal year 1989 funding and staff years for the three agencies able to identify the amount of resources devoted to food safety and quality follow:

- USDA's Agricultural Research Service (ARS) performs food safety research, such as developing a methodology for detecting and controlling bacterial contamination of meat and poultry products. During fiscal year 1989 ARS used 168 scientist years and about \$25 million for food safety and quality activities.
- USDA's Animal and Plant Health Inspection Service (APIIIS) protects the nation's animal and plant resources from diseases and pests that indirectly affect food safety.
- The Treasury Department's Bereau of Alcohol, Tobacco and Firearms
 enforces the laws that cover the production, distribution, and labeling of
 alcoholic beverages, except wine beverages that contain less than 7 percent alcohol, which are the responsibility of FDA. By agreement with FDA
 the Bureau also has primary federal responsibility for ensuring the
 safety of alcoholic beverages.
- The Treasury Department's Customs Service assists other federal food safety and quality agencies in carrying out their responsibilities relating to imported foods, such as collecting samples of imports.
- HHS' Centers for Disease Control engages in public health activities related to food safety and quality, such as monitoring, identifying, and

investigating foodborne disease problems to determine their contributing factors. In fiscal year 1989 the Centers for Disease Control used about 25 staff years and about \$2.6 million for food safety and quality activities.

 The Federal Trade Commission regulates food advertising. In fiscal year 1989 the Federal Trade Commission used about 29 staff years and about \$2 million for food safety and quality activities.

Scope and Methodology

To accomplish our objectives, we discussed with officials of each federal agency included in our review its food safety and quality activities. We also gathered from the agencies their budget data and other program information relating to food safety and quality.

Although other federal agencies are involved with food safety and quality activities, we determined that the 12 agencies discussed in this report had the most significant roles. Our methodology for determining which agencies to include was based on identifying (1) the principal federal food safety and quality legislation, (2) the agencies responsible for implementing the legislation, and (3) the agencies with which the implementing agencies coordinated their activities.

We made our review from June 1989 through June 1990 in accordance with generally accepted government auditing standards. We did not verify the accuracy of the data and information the agencies provided to us because of the enormous volume provided.

We discussed the information contained in this report with responsible AMS, EPA, FDA, FGIS, FSIS, and NMFS officials, who generally agreed with the facts. Their comments have been incorporated into the report where appropriate. As requested, we did not obtain official agency comments on the report.

Appendix IX to this report discusses federal food safety and quality activities for meat and poultry products to illustrate the complexity and fragmentation of the federal system for regulating food safety and quality. A companion volume to this report, Food Safety and Quality:

Who Does What in the Federal Government (GAO/RCED-91-19B), presents more details on the food safety and quality activities of the 12 federal agencies discussed in this volume. Information is included on (1) major legislation. (2) organizational units and responsibilities, (3) program activities, (4) funding levels, (5) staffing levels, (6) agreements with

other federal agencies, and (7) critical food safety and quality issues of the 1990s.

As arranged with your offices, unless you publicly announce its contents earlier, we plan no rurther distribution of this report until 30 days from the date of this letter. At that time, we will send copies to the Secretary of Agriculture; the Secretary of Commerce; the Secretary of Health and Human Services; the Commissioner, Food and Drug Administration; the Administrator, Environmental Protection Agency; and other interested parties.

Please call me on (202) 275-5138 if you have any questions concerning the report. Other major contributors to this report are listed in appendix X.

John W. Harman Director, Food and

Agriculture Issues

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Abbreviations

AMA	Agricultural Marketing Act
AMS	Agricultural Marketing Service
APHIS	Animal and Plant Health Inspection Service
ARS	Agricultural Research Service
CDC	Centers for Disease Control
EPA	Environmental Protection Agency
EPIA	Egg Products Inspection Act
FDA	Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
FGIS	Federal Grain Inspection Service
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Ac
FMIA	Federal Meat Inspection Act
FSIS	Food Safety and Inspection Service
FY	fiscal year
GAO	General Accounting Office
HHS	Department of Health and Human Services
NMFS	National Marine Fisheries Service
NOAA	National Oceanic and Atmospheric Administration
PHSA	Public Health Service Act
PPLY	Poultry Products Inspection Act
USDA	U.S. Department of Agriculture
1 SGS \	U.S. Grain Standards Act

Principal Food Safety and Quality Legislation and Federal Agencies Responsible for Implementation

	USDA						
Legislation*	FDA	AMS	FGIS	FSIS	EPA	NMFS	
Agricultural Marketing Act of 1946 (AMA)	•	X	Х	•	•	×	
Agricultural Marketing Agreement Act of 1937	•	X	•	•	•		
Egg Products Inspection Act (EPIA)	Х	X	•	•	•		
Federal Ant: Tampering Act	X	Х	•	X	•		
Federal Food, Drug, and Cosmetic Act (FFDCA)	Х	•	•	•	Χ	(
Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)	•	•	•	•	X	1	
Federal Meat Inspection Act (FMIA)	•	•	•	X	•		
Federal Import Milk Act	X	•	•	•	•		
Infant Formula Act of 1980	Х	•	•	•	•		
Lacey Act	•	•	•	•	•	×	
Magnuson Fishery Conservation and Management Act	•	•	•	•	•	×	
National Ocean Pollution Research and Development and Monitoring Planning Act	•	•	•	•	•	X	
Pesticide Monitoring Improvements Act	Х	•	•	•	•		
Poultry Products Inspection Act (PPIA)	•	•	•	X	•		
Public Health Service Act (PHSA)	X	•	•	•	•		
Safe Drinking Water Act	X	•	•	•	×	•	
Toxic Substances Control Act	•	•	•	•	X		
U.S. Grain Standards Act (USGSA)	•	•	X	•			

^aThis lists 18 of the principal laws administered by these six agencies, which also administer 10 other less significant food safety and quality laws

Major Provisions of Principal Food Safety and Quality Legislation

The Agricultural Marketing Act of 1946 authorizes the Secretary of Agriculture to provide services upon request to inspect, certify, and identify the class, quality, quantity, and condition of agricultural products shipped or received in interstate commerce. The act also authorizes the Secretary to develop and improve standards of quality, quantity, condition, grade, and packaging and to recommend and demonstrate such standards in order to encourage uniformity and consistency in commercial practices.

AMS, FGIS, and NMFS develop standards and perform inspection and grading services under the act. AMS is responsible for dairy products, fruits and vegetables, livestock, meat, poultry, rabbits, and shell eggs. FGIS is responsible for rice, pulses, processed grain products, hops, and related commodities. NMFS is responsible for fish and shellfish.

The Agricultural Marketing Agreement Act of 1937 authorizes the establishment of programs and agreements to regulate the quality, quantity, or container or pack requirements for fruits, vegetables, and certain specialty crops and to regulate the minimum prices paid to producers of milk and dairy products. The act also requires the regulation of certain of these commodities imported into the United States whenever domestic shipments of the commodities are subject to quality regulations under a marketing order.

The Egg Products Inspection Act (1) requires continuous AMS inspection of all egg products processing plants; (2) requires mandatory quarterly inspections of shell egg handlers packing for consumer sales; (3) restricts certain types of shell eggs from moving into consumer channels; and (4) prohibits state or local governments from imposing standards differing from official USDA standards for grade and size of eggs moving in interstate commerce. Under the act AMS is responsible for inspecting egg product processing plants and firms marketing eggs, while FDA is responsible for restaurants, institutions, and food manufacturing establishments that serve eggs or use them in their products.

The Federal Anti-Tampering Act provides for monetary penalties and imprisonment for tampering with consumer products, including food, and their labeling and packaging that affect interstate and foreign commerce. The act gives FDA, USDA, and the Federal Bureau of Investigation the authority to follow up on tampering violations.

Appendix II Major Provisions of Principal Food Safety and Quality Legislation

The Federal Food, Drug, and Cosmetic Act authorizes FDA to (1) regulate food (except meat, poultry, and egg products, which are covered by separate legislation and are USDA's responsibility) production and manufacturing to ensure that food is safe, clean, and wholesome and (2) establish reasonable standards of identity, quality, and fill of container for food products. The act also (1) requires FDA to review and approve food and color additives before they can be marketed and (2) prohibits the interstate commerce of adulterated foods and false or misleading labeling of food products. Under the act EPA is responsible for setting tolerances for pesticide residues on food commodities and animal feed marketed in the United States.

The act also directs FDA to maintain surveillance of all animal drugs, feeds, and veterinary devices marketed in interstate commerce to ensure their compliance with the act. The act requires that all animal drugs that are not generally recognized as safe and effective be approved by FDA before marketing on the basis of studies made by the sponsor.

The Federal Insecticide, Fungicide, and Rodenticide Act requires EPA to register pesticide products, specify the terms and conditions of their use prior to being marketed, and remove unreasonably hazardous pesticides from the marketplace. The act requires EPA to take into account the economic, social, and environmental costs and benefits in making decisions.

The Federal Meat Inspection Act requires FSIS to administer an inspection program to ensure that meat and meat products moving in interstate and foreign commerce for use as human food are safe, wholesome, and correctly marked, labeled, and packaged. The act was amended in 1967 to establish the federal-state cooperative program under which USDA helps fund state inspection programs conducted by state employees for meat sold in intrastate commerce. It also required state inspection programs to be "at least equal to" the federal program and strengthened the regulation of imported meat.

Under the <u>Federal Import Milk Act</u>, milk and cream may be imported into the <u>United States only under a permit from the Secretary of Health and Human Services after certain sanitary and other prerequisites have been fulfilled.</u>

The Infant Formula Act of 1980 established nutrient requirements for infant formulas and gave FDA authority to establish requirements for quality control, record keeping, reporting, and recall procedures. The act also extended FDA's factory inspection authority to permit access to

Appendix II Major Provisions of Principal Food Safety and Quality Legislation

manufacturers' records and test results necessary to determine compliance.

The Lacey Act, administered by NMFS, makes it unlawful to deliver, carry, transport, or ship by any means for commercial or noncommercial purposes or sell in interstate or foreign commerce any fish or wildlife that was taken, transported, or sold in violation of any federal, state, or foreign law or regulation. NMFS investigates alleged violations of the act.

The Magnuson Fishery Conservation and Management Act, administered by NMFS, requires fishery resources to be used to the greatest overall benefit to the nation, with specific reference to the use of the nation's fishery resources as food. The act includes a mandate for NMFS programmatic activities to, among other things, maximize the quality of seafood products to ensure the greatest economic return for harvested resources.

The National Ocean Pollution Research and Development and Monitoring Planning Act of 1978 requires the National Oceanic and Atmospheric Administration (NOAA) to develop the necessary base of information to protect public health and provide for the rational, efficient, and equitable conservation and development of ocean and coastal resources.

The Pesticide Monitoring Improvements Act of 1988 requires FDA to (1) develop new, or modify existing, data management systems to track, summarize, and evaluate pesticide monitoring data; (2) enter into cooperative agreements with foreign countries to obtain pesticide usage data on crops imported from those countries; and (3) develop an analytical methods research plan to guide the development of methods to improve the efficiency of food monitoring.

The Poultry Products Inspection Act requires FSIs to administer an inspection program to ensure that poultry and poultry products moving in interstate and foreign commerce for use as human food are safe, wholesome, and correctly marked, labeled, and packaged. The act was amended in 1968 to establish the federal-state cooperative program under which USDA helps fund state inspection programs conducted by state employees for poultry products sold in intrastate commerce. It also required state inspection programs to be "at least equal to" the federal program.

The Public Health Service Act provides for federal-state cooperative assistance in preventing the interstate transmission of disease, and thus

Appendix II Major Provisions of Principal Food Safety and Quality Legislation

establishes FDA's authority for its programs for sanitation in milk processing, shellfish, restaurant and retail market operations, and interstate travel conveyances.

The Safe Drinking Water Act requires FDA, in consultation with EPA, to establish regulations relating to bottled drinking water standards. Pursuant to the act FDA has established standards of quality and current good manufacturing practice regulations for processing and bottling waters. EPA has jurisdiction over drinking water produced by municipal systems of a certain size but not over individual private wells.

Under the <u>Toxic Substances Control Act</u>, EPA controls the manufacturing, processing, distribution, use, and disposal of chemical substances and mixtures, including those that can adulterate food.

The U.S. Grain Standards Act, administered by FGIS, (1) requires a national inspection and weighing system for grain, (2) requires that most export grain be inspected and weighed, (3) provides for inspection and weighing services for domestic grain upon request, (4) prohibits deceptive practices and criminal acts with respect to inspecting and weighing grain, and (5) provides penalties for violations. The act was amended in 1981 to require FGIS to collect user fees from official agencies (states and private agencies that perform inspection and weighing services) to fund the costs associated with supervising the federal grain inspection and weighing activities of official agencies.

Responsibilities, Funding, and Staffing of Principal Federal Agencies Involved With Food Safety and Quality

Millions of do	ollars				
Agency	Program	Principal legislation	Responsible for	FY 1989 funding	FY 1989 staffing
FDA	Food safety	FFDCA PHSA	Safety/quality of all foods except meat and poultry: shares eggs with AMS	\$132	2.093
	Animal drugs and feeds	FFDCA	Safety/effectiveness of animal drugs and feeds; safety of food animals	26	244
USDA	The second secon	THE PERSON OF THE PARTY PARTY AND ADDRESS OF THE PARTY AND ADDRESS OF T			passens with appearance or in servi
FSIS	Meat and poultry inspection	FMIA PPIA	Safety/quality of meat and poultry	457	10.399
AMS	Egg products inspection shell egg surveillance Commodity	EPIA AMA	Safety/quality of egg products and shell eggs Facilitate marketing of agricultural commodities	10	201
	standardization, inspection, and grading, other			87	2.171
FGIS	Grain standardization grain/rice inspection and weighing	USGSA AMA	Facilitate marketing of grain and rice	42	860
NMFS	Seafood inspection and research	AMA	Voluntary seafood inspection/grading and research	12	265
EPA	Pesticide registration and tolerances	FIFRA FFDCA	Safety of pesticide products	55	624
Total				\$821	16,857

Types of Food Safety and Quality Activities Carried Out by Principal Federal Agencies

		USDA				* present
Activity	FDA	AMS	FGIS	FSIS	EPA	NMFS
Inspections	Х	X	X	Χ	X	>
Quality grading	•	X	X	•	•	×
Collect/analyze samples	Х	X	X	χ	X	×
Research	X	a	a	a	X	×
Develop standards for						
Foods/crops	Х	Х	Х	•	•	X
Facilities	Х	X	•	Х	•	
Equipment	•	X	X	X	•	
Processing procedures	X	X	•	X	•	
Labels	X	Χ	•	•	X	
Packaging	•	X	•	•	X	×
Approve before use		6 W				
Facilities	•	X	•	Χ	•	
Equipment	•	X	Χ	X	•	
Processing procedures	•	X	•	Χ	•	
Product recipes/formulas	•	X		X	•	··· ×
Labels	•	X	•	X	X	
Packaging	•	X	•	•	•	
Food colors/additives	X	•	•	•	•	
Animal drugs/food additives	X	•	•	•	•	
Pesticide products	•	•	•	•	X	
Set residue tolerances for						
Pesticides	•	•	•	•	X	•
Other contaminants	Χ	•	•	•	•	

^aAgricultural Research Service carries out research for AMS_FGIS_and FSIS

Federal Agencies Responsible for Regulating, Monitoring, or Performing Quality Grading Services for Various Food Industries

	100 G 1 / N 1 /						
		USDA					
FDA	AMS	FGIS	FSIS	EPA	NMFS		
X	X	•	•	X	•		
X	Х	•	•	X	•		
X	Х	•	•	X	•		
X	•	Х	•	X	•		
X	•	•	•	•	•		
•	Х	•	Х	X	•		
X	•	•	•	•	•		
X	•	•	•	X	X		
	FDA X X	FDA AMS X X X X X X	USDA FDA AMS FGIS	USDA FDA AMS FGIS FSIS	USDA FDA AMS FGIS FSIS EPA X X • • X X X • • X X X • • X		

Examples of Federal Interagency Agreements Relating to Food Safety and Quality

				the state of		
			USDA			
Subject of agreement	FDA	AMS	FGIS	FSIS	EPA	NMFS
Coordination of federal regulatory activities concerning residues of drugs, pesticides, and environmental contaminants that may adulterate food	X	X	•	×	X	•
Inspection of food manufacturing firms whose facilities are under the jurisdiction of both FSIS and FDA	X	•	•	×	•	•
Recall of meat/poultry products prepared in an FSIS-inspected establishment that contain food ingredients recalled by FDA	X	•		X	•	•
Jurisdiction relating to administering the Egg Products Inspection Act	×	Х	•	•	•	•
Coordination of inspection activities relating to dry-milk-product plants under voluntary AMS inspection programs to determine whether products are contaminated with salmonella microorganisms	X	X	•	•	•	•
Coordination of inspection activities at feod (including fruits and vegetables) processing plants operating under AMS resident-type inspection/grading contracts which are also subject to FDA inspection	X	x	•	•	•	•
Coordination of inspection activities at facilities that process, hold, or distribute grain, rice, or pulses where an FGIS inspector or licensee is stationed which are also subject to FDA inspection.	X	•	X		•	•
Chardination of insection actifies at linery monities plants under NMFS voluntary inspection contracts which are also jubject to FDA inspection.	X	•		•		X

Changes in Staffing and Funding Levels of Principal Federal Agencies Involved With Food Safety and Quality Activities, Fiscal Years 1980, 1985, and 1989

 Section 1. 	e venezación	20 July 18 10		
Staffing level for fiscal year				
1980	1985	1989		
11 084	*5 eT2	995 ز		
2 530	2 336	2,337		
1 778	733	750		
755	591	624		
Funding le	evel for fiscal y	ear		
Millions of (c	anstant 1989- d	oliars		
\$ 469 1	\$ 469.5	\$ 457.2		
172 2	155.3	158.3		
85 3	44 6	42 3		
59 4	51.7	54.7		
	1980 11 084 2 530 1 778 755 Funding le Millions of (c \$469 1 172 2 85 3	1980 1985 11 084 10 672 2 530 2 336 1 776 7 70 755 531 Funding level for fiscally Millions of (constant 1980 d \$469 1 \$469 5 172 2 155 3 85 3 44 6		

Note. We did not include AMS and NMES in this appendix because the agencies id dinor provide staffing and funding data for all 3 fiscal years, principally because of changes in organization and or responsibilities or destruction of data pursuant to agency records retention gaigetines.

Critical Food Safety Issues of the 1990s as Perceived by Officials of Principal Federal Agencies

Food safety issue	٠.		1 y- p i	.2.5	1425	amentage.
	FDA	USDA				
		AMS	FGIS	FSIS	EPA	NMFS
Microbiological contamination	X	X	X	X	•	X
Pesticide/chemical contamination	X	X	X	X	X	X
Foods produced using biotechnology	X	X	•	•	X	
Pollutarits/contaminants/toxins in seafood	X	•	•	•	•	X
Cleansing of contaminated shellfish	•	•	•	•	•	X
Potential hazards associated with new processing, packaging, and marketing techniques	•		•	•	•	X
Adequate water of acceptable quality for seafood processing	•	•		•	•	X
Animal feed produced by biotechnology	X	•	•	•	•	•
Industrial by-product feed for animals	X	•	•	•	•	
Pesticide/chemical cuintamination of animal feed	X	•	•	•	X	
Lengthy FIFRA cancellation process	•	•	•	•	X	•
Compatibility of FFDCA and FIFRA tolerance provisions		•	•	•	X	•
Difficulty in removing pesticides from the market		•	•	•	Х	•
Weak FIFRA penalties for violations	•	•	•	•	X	•

Federal Food Safety and Quality Activities Relating to Meat and Poultry Products

The current federal food safety and quality system, which is complex and fragmented, relies on the cooperation of federal, state, local, and international agencies and private industry. Meat and poultry safety and quality activities illustrate this complexity and fragmentation.

This appendix presents information on the size and makeup of the industry, federal legislative responsibilities, federal food safety and quality activities, federal interagency agreements, relationship to state inspection programs, and critical food safety issues of the 1990s related to meat and poultry.

FSIS is the principal federal agency performing meat and poultry safety and quality activities. Other federal agencies, such as FDA, EPA, AMS, APHIS, and ARS, also carry out meat and poultry safety and quality activities.

Size and Makeup of the Meat and Poultry Industry

According to FSIS, in fiscal year 1989:

- About 6,700 meat and poultry plants throughout the United States and 220 official import establishments were subject to federal inspection.
- All of the federally inspected meat plants and federally inspected poultry plants were eligible to receive voluntary grading and certification services from AMS.
- About 5,700 meat and poultry plants engaged in intrastate commerce were inspected by states under their own meat and poultry inspection programs.
- About 1,400 plants in 34 countries were certified by rsis to export meat or poultry to the United States.
- About 2.5 billion pounds of meat and poultry were imported into the United States and about 2.6 billion pounds were exported.

Further, FDA estimates that about 80 percent of the livestock and poultry in the United States is treated with some animal drug or feed additive and that its animal drug data system contains information on over 12,000 animal drug products.

Federal Legislative Responsibilities

FSIS is responsible for ensuring that the nation's commercial supply of meat and poultry products is safe, wholesome, and correctly marked, labeled, and packaged, as required by law. In carrying out its responsibilities, FSIS Appendix IX Federal Food Safety and Quality Activities Relating to Meat and Poultry Products

- inspects animals intended for use as food before and after slaughter and supervises the further processing of meat and poultry products;
- provides pathological, microbiological, chemical, and other scientific examination of meat and poultry products for disease, infection, contamination, or other types of adulteration;
- reviews and approves a plant's plans for facilities, equipment, and procedures to make sure the operation will be sanitary before the plant can begin operating as a federally inspected establishment;
- reviews and approves formulas and labels of meat products containing ever 3 percent fresh meat and poultry products containing 2 percent or more cooked poultry before the products are marketed;
- reviews and assesses the effectiveness of state meat and poultry inspection programs for plants under state jurisdiction to ensure that states apply standards at least equal to those of the federal program:
- reviews and assesses foreign inspection systems and plants that export meat and poultry to the United States to ensure that standards are maintained equal to those in the United States; and
- reinspects imported meat and poultry products at port of entry to ensure that products meet federal standards.

FDA is responsible for ensuring that animal drugs and feeds marketed in interstate commerce are safe and effective and produce no human health hazards when used in food-producing animals. In carrying out its responsibilities, FDA

- reviews and evaluates applications for new animal drugs and food additives for effectiveness, animal safety, environmental impact, labeling, and human safety;
- inspects animal drug manufacturing and distribution facilities and medicated-feed manufacturing sites for compliance with FFIX's and FDS regulations; and
- collects and analyzes animal drug and animal feed samples for compliance with FFIXA and FDA regulations.

By agreement with FSIS, FDA also is responsible for the safety and quality of meat products containing 3 percent or less fresh meat and poultry products containing less than 2 percent cooked poultry.

EPA is responsible for analyzing potential health impacts and setting tolerances for pesticide residues on meat and poultry products and animal feeds marketed in the United States. FDA, USDA, and state enforcement agencies are responsible for enforcing the tolerances.

Appendix IX
Federal Food Safety and Quality Activities
Relating to Meat and coultry Products

AMS is responsible for developing standards of quality, quantity, condition, grade, and packaging for meat and poultry and for performing grading and inspection services upon request for a fee.

APHIS is responsible for conducting programs to prevent communicable animal diseases of foreign origin from entering the United States and preventing the spread of animal diseases through interstate shipments of livestock.

Major Federal Activities

In carrying out its meat and poultry inspection activities during fiscal year 1989, FSIS

- inspected about 35.4 billion pounds of slaughtered meat.
- inspected about 29.6 billion pounds of slaughtered poultry,
- inspected about 74.1 billion pounds of processed meat products.
- inspected about 80.9 billion pounds of processed poultry products,
- · inspected about 2.5 billion pounds of imported meat and poultry, and
- analyzed 564,050 samples of meat and poultry.

In performing its voluntary grading and certification services during fiscal year 1989, ams

- graded about 14.6 billion pounds of meat.
- · graded about 14.4 billion pounds of poultry, and
- · certified 759 million pounds of meat.

Federal Interagency Agreements

Coordination of meat and poultry safety and quality activities takes place between FSIS, FDA, EPA, AMS, APHIS, and ARS. Following are examples of the agreements:

- FSIS, FDA, EPA, and AMS have an agreement establishing the working relationships for promoting more effective, efficient, and coordinated federal regulatory activities concerning residues of drugs, pesticides, and environmental contaminants that may adulterate meat, poultry, eggs, or animal feed.
- FSIS and FDA have an agreement that is intended to minimize duplication of inspection effort by exchanging work planning information and referring violative conditions concerning food manufacturers whose facilities are under the jurisdiction of both FSIS and FDA.

Appendix IX
Federal Food Safety and Quality Activities
Relating to Meat and Poultry Products

- FSIS and FDA have an agreement pertaining to meat and poultry products that have been manufactured in an FSIS-inspected establishment and that contain food ingredients that have been recalled by FDA.
- FSIS and AMS have an agreement covering meat and poultry plants where FSIS provides mandatory inspection services and AMS provides voluntary grading services.
- FSIS and APHIS have an agreement involving surveillance, testing, investigation, and tracebacks to points of origin of diseased animals.
- FSIS and ARS have an agreement relating to planning, budgeting, and managing studies on chemical residues in meat and conducting chemical and microbiological analysis on meat samples.
- FSIS and ARS have an agreement involving research on meat and poultry products done by ARS for FSIS.

Relationship to State Inspection Programs

Pursuant to the Talmadge-Aiken Act of 1962, FSIS established cooperative agreements with states to permit state employees to carry out inspection in meat and poultry slaughtering and processing plants. These plants are considered to be "federally inspected" and thus may sell their products in interstate commerce.

Under the federal-state cooperative inspection program, FSIS monitors state inspection programs that inspect meat and poultry products that will be sold only within the state in which they are produced. The purpose is to ensure that states apply inspection standards that are at least equal to those of the federal program. About half the states conduct their own meat and poultry inspection programs, and about 5,700 plants are inspected by state programs. If states choose to end their state inspection programs or cannot maintain the "at least equal to" standard, FSIS must assume responsibility for inspection.

AMS has cooperative agreements with 11 states regarding voluntary meat grading and certification services and with all 50 states, the Virgin Islands, and Puerto Rico regarding poultry grading.

APHIS cooperates with states to control and eradicate animal diseases present in the United States.

Critical Food Safety Issues of the 1990s

Meat and poultry pose a wide array of potential health problems, including microbiological contamination such as Salmonella and Listeria monocytogenes; chemical and drug residues from pesticides, animal drugs, and medicated feeds; parasites; and decomposition.

Appendix IX
Federal Food Safety and Quality Activities
Relating to Meat and Poultry Products

According to FSIS, it will face three critical issues during the 1990s. FSIS believes that

- the United States needs a strong food safety research program to uncover more information about emerging foodborne pathogens (bacteria and viruses capable of causing disease in humans) and to find better ways to control all pathogens;
- more research, including development of additional rapid tests for chemical residue detection, is needed; and
- it is necessary to modernize meat and poultry inspection.

FDA's Center for Veterinary Medicine provided the following list of critical food safety issues of the 1990s:

- Mycotoxin contamination of grains and other feedstuffs and the control procedures used.
- Pesticide and industrial chemical contamination of feeds and feed ingredients.
- Microbiological contamination of feed ingredients and the control procedures used.
- · Feed products produced using biotechnology.
- The by-product feed ingredient industry, especially industrial wastes used as feed ingredients.
- · Drug and chemical residues in meat.

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